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\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Practice limited to  
Federal Agencies

March 7, 2005

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**WRITER'S DIRECT NUMBER:**  
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**INTERNET ADDRESS:**  
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**Mail Stop Amendment**

Re: U.S. Utility Patent Application  
Appl. No. 10/686,713; Filed: October 17, 2003  
For: **Molecular Detection Systems Utilizing Reiterative Oligonucleotide  
Synthesis**  
Inventor: Michelle M. Hanna  
Our Ref: 2072.0010006/LBB/SJE

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (21 sheets citing 102 documents);
3. 1 document cited in Form PTO-1449 (attached); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

*Michelle A. Cimbala*  
Reg. No. 33851  
*for* Lawrence B. Bugaisky  
Attorney for Applicant  
Registration No. 35,086

LBB/SJE/lam  
Enclosures

371219.1

IPW

the PTO did not receive the following listed items(s) we did not receive exp. me for amendment.



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Hanna, Michelle M.

Appl. No.: 10/686,713

Filed: October 17, 2003

For: **Molecular Detection Systems  
Utilizing Reiterative  
Oligonucleotide Synthesis**

Confirmation No.: 9587

Art Unit: 1637

Examiner: Young J. Kim

Atty. Docket: 2072.0010006/LBB/SJE

**Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents AA1-AK1, AA2-AK2, AA3-AK3 and AA4-AC4 are not provided in accordance with the Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan, effective October 21, 2004, which states "section 1.98(a)(2)(i) is amended to eliminate the requirement in paragraph (a)(2)(i) for a copy of each U.S. patent or U.S. patent application publication listed in an IDS in a patent application regardless of the filing date of the application."

A copy of document AN1 is provided. With the exception of document AN1, copies of the remaining non-patent documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/984,664, filed October 30, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

The Examiner's attention is directed to the following list of related co-pending patent applications, which are directed to related technical subject matter:

U.S. Application No. 10/488,971, filed March 9, 2004, cited herein as document AR21;

U.S. Application No. 10/976,240, filed October 24, 2004, cited herein as document AS21;

International Application No. PCT/US2004/035740, filed October 29, 2004, cited herein as document AT21;

U.S. Application No. 09/984,664, filed October 30, 2001, published as 2003/0099950 A1 and cited as document AI3;

U.S. Application No. 10/425,037, filed April 29, 2003, published as 2004/0054162 A1 and cited herein as document AJ3;

U.S. Application No. 10/600,581, filed June 23, 2003, published as 2004/0137461 A1 and cited herein as document AK3;

U.S. Application No. 10/602,045, filed June 24, 2003, published as 2004/0234996 A1 and cited herein as document AA4;

U.S. Application No. 10/790,766, filed March 3, 2004, published as 2004/0157257 A1 and cited herein as document AB4; and

U.S. Application No. 10/607,136, filed June 27, 2003, published as 2005/0026150 A1 and cited herein as document AC4.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

It is also requested that the Examiner review the prosecution and cited art in the parent U.S. Application No. 09/984,664 in accordance with MPEP 2001.06(b), and indicate in the next communication from the office, in the present application, that the art cited in the earlier prosecution history has been reviewed in connection with the present application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is

not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

*Michelle A. Ambrose*  
Reg. No. 33851  
*for* Lawrence B. Bugaisky  
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Registration No. 35,086

Date: March 7, 2005

1100 New York Avenue, N.W.  
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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
2072.0010006/LBB/SJEAPPLICATION NO.  
10/686,713FIRST NAMED INVENTOR  
Hanna, M.M.FILING DATE  
October 17, 2003ART UNIT  
1637

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	3,996,345	12/07/1976	Ullman <i>et al.</i>			06/30/1975
	AB1	4,351,760	09/28/1982	Khanna <i>et al.</i>			09/07/1979
	AC1	4,582,788	04/15/1986	Erllich			01/07/1983
	AD1	4,683,194	07/28/1987	Saiki <i>et al.</i>			03/28/1985
	AE1	4,739,044	04/19/1988	Stabinsky			06/13/1985
	AF1	4,757,141	07/12/1988	Fung <i>et al.</i>			08/26/1985
	AG1	4,786,600	11/22/1988	Kramer <i>et al.</i>			05/25/1984
	AH1	5,130,238	07/14/1992	Malek <i>et al.</i>			08/23/1989
	AI1	5,169,766	12/08/1992	Schuster <i>et al.</i>			06/14/1991
	AJ1	5,399,491	03/21/1995	Kacian <i>et al.</i>			03/19/1992
	AK1	5,503,979	04/02/1996	Kramer <i>et al.</i>			08/26/1994

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 89/01050	02/09/1989	WIPO			Yes No
	AM1	WO 03/038042 A2	05/08/2003	WIPO			Yes No
	AN1	WO 04/096997	11/11/2004	WIPO			Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Agrawal, S. and Tang, J.Y., "Site-specific functionalization of oligodeoxynucleotides for non-radioactive labeling," <i>Tetrahedron Lett.</i> 31:1543-1546, Pergamon Press (1990)
AS	1	Antequerra, F. and Bird, A., "Number of CpG islands and genes in human and mouse," <i>Proc. Natl. Acad. Sci. USA</i> 90:11995-11999, National Academy of Sciences (1993)
AT	1	Callahan, R., <i>et al.</i> , "Frequent Mutations in Breast Cancer," <i>Ann. N.Y. Acad. Sci.</i> 698:21-30, New York Academy of Sciences (1993)

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449  <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 2072.0010006/LBB/SJE	APPLICATION NO. 10/686,713
	FIRST NAMED INVENTOR Hanna, M.M.	
	FILING DATE October 17, 2003	ART UNIT 1637

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,508,178	04/16/1996	Rose <i>et al.</i>			02/09/1994
	AB2	5,554,516	09/10/1996	Kacian <i>et al.</i>			12/02/1993
	AC2	5,571,669	11/05/1996	Lu <i>et al.</i>			01/14/1993
	AD2	5,595,891	01/21/1997	Rose <i>et al.</i>			07/19/1990
	AE2	5,648,211	07/15/1997	Fraiser <i>et al.</i>			04/18/1994
	AF2	5,654,142	08/05/1997	Kievits <i>et al.</i>			03/14/1995
	AG2	5,679,512	10/21/1997	Laney <i>et al.</i>			08/20/1993
	AH2	5,683,879	11/04/1997	Laney <i>et al.</i>			06/07/1995
	AI2	5,744,308	04/28/1998	Guillou-Bonnici <i>et al.</i>			07/26/1995
	AJ2	5,766,849	06/16/1998	McDonough <i>et al.</i>			11/28/1994
	AK2	5,824,517	10/20/1998	Cleuziat <i>et al.</i>			05/16/1997

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	2	Chamberlin, M.J., "Bacterial DNA-Dependent RNA Polymerases," in The Enzymes, Boyer, P.D., ed., Academic Press, New York, N.Y. pp. 61, 84-86 (1982)
	AS	2	Cheung, V.G., <i>et al.</i> , "A resource of mapped human bacterial artificial chromosome clones," <i>Genome Research</i> 9:983-993, Cold Spring Laboratory Press (1999)
	AT	2	Cifone, M.A. and Fidler, I.J., "Increasing metastatic potential is associated with increasing genetic instability of clones isolated from murine neoplasms," <i>Proc. Natl. Acad. Sci. USA</i> 78:6949-6952, National Academy of Sciences (1981)

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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	5,858,801	10/12/1999	Brizzolara			03/13/1997
	AB3	5,888,819	03/30/1999	Goelet <i>et al.</i>			03/05/1991
	AC3	6,008,334	12/28/1999	Hanna			07/23/1997
	AD3	6,107,037	08/22/2000	Sousa <i>et al.</i>			06/19/1998
	AE3	6,107,039	08/22/2000	Hanna			10/02/1998
	AF3	6,114,519	07/05/2000	Cole <i>et al.</i>			10/15/1997
	AG3	6,251,594	06/26/2001	Gonzalzo <i>et al.</i>			06/09/1998
	AH3	2002/0168641	11/14/2002	Mortensen <i>et al.</i>			03/09/2001
	AI3	2003/0099950 A1	05/29/2003	Hanna			10/30/2001
	AJ3	2004/0054162 A1	03/18/2004	Hanna			04/29/2003
	AK3	2004/0137461 A1	07/15/2004	Hanna			06/23/2003

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	3	Costas, C., <i>et al.</i> , "RNA-protein crosslinking to AMP residues at internal positions in RNA with a new photocrosslinking ATP analog," <i>Nucleic Acids Res.</i> 28:1849-1858, Oxford University Press (May, 2000)
	AS	3	Daube, S.S. and von Hippel, P.H., "Functional Transcription Elongation Complexes from Synthetic RNA-DNA Bubble Duplexes," <i>Science</i> 258:1320-1324, American Association for the Advancement of Science (1992)
	AT	3	Dunn, J.J. and Studier, F.W., "Complete Nucleotide Sequence of Bacteriophage T7 DNA and the Locations of T7 Genetic Elements," <i>J. Mol. Biol.</i> 166:477-535, Academic Press, Inc. (1983)

EXAMINER

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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	2004/0234996 A1	11/25/2004	Hanna			06/24/2003
	AB4	2004/0157257 A1	08/12/2004	Hanna			03/03/2004
	AC4	2005/0026150 A1	02/03/2005	Hanna			06/27/2003
	AD						
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**FOREIGN PATENT DOCUMENTS**

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>4</u>	Esteller, M., <i>et al.</i> , "Promoter Hypermethylation and BRCA1 Inactivation in Sporadic Breast and Ovarian Tumors," <i>J. Natl. Cancer Inst.</i> 92:564-569, Oxford University Press (April, 2000). (Retrieved from LexisNexis Academic database)
	AS	<u>4</u>	Frommer, M., <i>et al.</i> , "A genomic sequencing protocol that yields a positive display of 5-methylcytosine residues in individual DNA strands," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 89:1827-1831, National Academy of Sciences (1992)
	AT	<u>4</u>	Gait, M.J., <i>et al.</i> , "Oligoribonucleotide synthesis," in <i>Oligonucleotides and Analogues</i> , Eckstein, F., ed., Oxford University Press, Oxford, Great Britain, pp. 25-31 (1992)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>5</u>	Gait, M.J., "An Introduction to Modern Methods of DNA Synthesis," in Oligonucleotide synthesis: a practical approach, Gait, M.J., ed., Oxford University Press, Oxford, Great Britain, pp.1-22 (1984)
	AS	<u>5</u>	Geider, K., et al., "An RNA transcribed from DNA at the origin of phage fd single strand to replicative form conversion," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 75:645-649, National Academy Press (1978)
	AT	<u>5</u>	Giusti, W.G. and Adriano, T., "Synthesis and Characterization of 5'-Fluorescent-dye-labeled Oligonucleotides," <i>PCR Methods Appl.</i> 2:223-227, Cold Spring Harbor Laboratory Press (1993)

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>6</u>	Guatelli, J.C., <i>et al.</i> , "Isothermal, in vitro amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 87:1874-1878, National Academy Press (1990)
AS	<u>6</u>	Gupta, K.C., <i>et al.</i> , "A general method for the synthesis of 3'-sulfhydryl and phosphate group containing oligonucleotides," <i>Nucleic Acids Res.</i> 19:3019-3025, Oxford University Press (1991)
AT	<u>6</u>	Gurevich, V.V., <i>et al.</i> , "Preparative in Vitro mRNA Synthesis Using SP6 and T7 RNA Polymerases," <i>Anal. Biochem.</i> 195:207-213, Academic Press, Inc. (1991)

EXAMINER

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	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>I</u>	Hanna, M.M., "Photoaffinity Cross-Linking Methods for Studying RNA-Protein Interactions," <i>Methods Enzymol.</i> 180:383-409, Academic Press, Inc. (1989)
	AS	<u>I</u>	Hanna, M.M., <i>et al.</i> , "Probing the environment of nascent RNA in Escherichia coli transcription elongation complexes utilizing a new fluorescent ribonucleotide analog," <i>Nucleic Acids Res.</i> 27:1369-1376, Oxford University Press (1999)
	AT	<u>I</u>	Hanna, M.M., <i>et al.</i> , "Synthesis and characterization of a new photocrosslinking CTP analog and its use in photoaffinity labeling E.coli and T7 RNA polymerases," <i>Nucleic Acids Res.</i> 21:2073-2079, Oxford University Press (1993)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>8</u>	He, B., <i>et al.</i> , "Preparation of probe-modified RNA with 5-mercapto-UTP for analysis of protein-RNA interactions," <i>Nucleic Acids Res.</i> 23:1231-1238, Oxford University Press (1995)
	AS	<u>8</u>	Herman, J.G., <i>et al.</i> , "Inactivation of the <i>CDKN2/p16/MTS1</i> gene is frequently associated with aberrant DNA methylation in all common human cancers," <i>Cancer Res.</i> 55:4525-4530, American Association for Cancer Research (1995)
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	FIRST NAMED INVENTOR Hanna, M.M.	
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	AR	<u>9</u>	Horii, A., <i>et al.</i> , "Frequent Replication Errors at Microsatellite Loci in Tumors of Patients with Multiple Primary Cancers," <i>Cancer Res.</i> 54:3373-3375, American Association for Cancer Research (1994)
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	AR	<u>10</u>	Kwoh, D.Y., <i>et al.</i> , "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 86:1173-1177, National Academy Press (1989)
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	AR	<u>11</u>	Loeb, L.A., "Mutator Phenotype May Be Required for Multistage Carcinogenesis," <i>Cancer Res.</i> 51:3075-3079, American Association for Cancer Research (1991)
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	AR	<u>12</u>	Meinkoth, J. and Wahl, G., "Hybridization of Nucleic Acids Immobilized on Solid Supports," <i>Anal. Biochem.</i> 138:267-284, Academic Press, Inc. (1984)
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	AR	<u>13</u>	Montemagno, C. and Bachand, G., "Constructing nanomechanical devices powered by biomolecular motors," <i>Nanotechnology</i> 10:225-231, IOP Publishing, Ltd. (1999)
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	AR	<u>14</u>	Nelson, P.S., <i>et al.</i> , "Bifunctional oligonucleotide probes synthesized using a novel CPG support are able to detect single base pair mutations," <i>Nucleic Acids Res.</i> 17:7187-7194, Oxford University Press (1989)
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	AR	<u>15</u>	Pringsheim, P., "Fluorescence of organic compounds," in Fluorescence and phosphorescence, Pringsham, P., ed., Interscience Publishers, Inc. New York, N.Y., pp. 392-397, 420-423 (1949)
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	AR	<u>16</u>	Robertson, K.D., "DNA methylation, methyltransferases, and cancer," <i>Oncogene</i> 20:3139-3155, Nature Publishing Group (May, 2001)
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	AR	<u>18</u>	Tlsty, T.D., <i>et al.</i> , "Differences in the rates of gene amplification in nontumorigenic and tumorigenic cell lines as measured by Luria-Delbrück fluctuation analysis," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 86:9441-9445, National Academy of Sciences (1989)
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	AT	<u>18</u>	Toyota, M. and Issa, J.P.J., "The role of DNA hypermethylation in human neoplasia," <i>Electrophoresis</i> 21:329-333, Wiley-VCH Verlag GmbH (January, 2000)

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	AT	<u>20</u>	International Search Report for International Application No. PCT/US02/34419, mailed July 24, 2003, International Search Authority/USA, Washington, D.C.

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	AR	<u>21</u>	Co-pending US Application No. 10/488,971, inventor Hanna, M., filed March 9, 2004 (NOT PUBLISHED)
	AS	<u>21</u>	Co-pending US Application No. 10/976,240, inventor Hanna, M., filed October 24, 2004 (NOT PUBLISHED)
	AT	<u>21</u>	Co-pending International Application No. PCT/US2004/035740, inventor Hanna, M., filed October 29, 2004 (NOT PUBLISHED)

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